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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALAIN FOUERE and PIERRE BIGE

Appeal 2008-6253
Application 10/787,170
Technology Center 3700

Decided:¹ January 30, 2009

Before DONALD E. ADAMS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 CFR § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is a decision on appeal from the Examiner's final rejection of claims 1-23. Jurisdiction for the appeal is under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The claims are directed to plug for the lachrymal duct. "The normal functioning of the human eye requires that its outer surface be constantly covered with a lubricating film constituted by tears, that ensure both rinsing and protection due to the natural anti-infectious antibiotics that they contain" (Spec. ¶ 4). "The deficiency in maintaining the stability of this film on the eyeball can cause . . . stinging, irritations, burning sensations and sight deterioration in the case of dryness on the eye surface." (*id.* at ¶ 5.) Tears (or lachrymal fluid) are manufactured by a series of glands in the eye (*id.* at ¶ 4). The lachrymal duct drains tears from the eye into the nasal cavity (*id.* at ¶¶ 4, 6). The claimed invention is a lachrymal plug which blocks the flow of tears into the nasal cavity, allowing the tears to accumulate in the eye and provide greater moisture to its surface (*id.* at ¶¶ 9, 15).

Claims 1-23 are pending. The claims stand rejected by the Examiner as follows:

Claims 1-9, 11, and 18-20 under 35 U.S.C. § 102(e) as anticipated by Webb et al. (US 6,629,533 B1, Oct. 7, 2003) (Ans. 4);

Claims 10, 15, and 21 under 35 U.S.C. § 103(a) as obvious in view of Webb and MacKeen et al. (US 4,915,684, Apr. 10, 1990) (Ans. 5);

Claims 12 and 13 under 35 U.S.C. § 103(a) as obvious in view of Webb and Freeman (US 3,949,750, Apr. 13, 1976) (Ans. 6).

Claim 14 under 35 U.S.C. § 103(a) as obvious in view of Webb and Herrick (US 5,163,959, Nov. 17, 1992) (Ans. 7).

Claims 16, 17, 22, and 23 under 35 U.S.C. § 103(a) as obvious in view of Webb and Seder et al. (US 4,959,048, Sep. 25, 1990) (Ans. 7).

The following claims are representative:

1. A lachrymal plug that allows a blockage of the lachrymal ducts to overcome a deficiency of the lachrymal glands by decreasing or suppressing the flow of tears toward the nasal cavities, the lachrymal plug comprising:
a substantially cylindrical body having an external lateral wall; and
flexible elements attached to the external wall structured and arranged to straighten out when positioned to maintain said lachrymal plug in position.
19. A method of positioning a lachrymal plug, the method comprising:
positioning in a lachrymal duct a substantially cylindrical body having external lateral wall and flexible elements attached to the external wall structured and arranged to straighten out when positioned to maintain the lachrymal plug.

PRINCIPLES OF LAW

Because the hallmark of anticipation is prior invention, the prior art reference – in order to anticipate under 35 U.S.C. § 102 – must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed.Cir.1983).

Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1369 (Fed. Cir. 2008).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on “inherency” under 35 U.S.C. § 102, on “prima facie obviousness” under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same,

and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) (footnote omitted).

“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

“[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727, 1741 (2007).

ISSUES

For the anticipation rejection, the issues are:

Does Webb describe a lachrymal plug with “flexible elements” which are “structured and arranged to straighten out when positioned to maintain said lachrymal plug” as recited in claims 1 and 19?

Does Webb describe the specific limitations recited in claims 2-9, 11, 18, and 20?

For the obviousness rejections, the issue is:

Did the Examiner err in finding that persons of ordinary skill in the art would have been prompted to have combined Webb with the secondary references (MacKeen, Freeman, Herrick, or Seder) to have made the claimed invention?

ANTICIPATION REJECTION

Claims 1-9, 11, and 18-20 stand rejected under 35 U.S.C. § 102(e) as anticipated by Webb (Ans. 4).

Findings of Fact (FF)

The Webb patent

1. Webb describes a canalicular or punctum plug which is placed into the punctal opening of the lachrymal duct to occlude the flow of tears through the duct (Webb, at col. 1, ll. 14-16; at col. 2, ll. 18-20; *see* Figs. 2a, 2b, 3a, and 3b).
2. The punctum plug² “generally includes a shaft and a head at a proximal end of the shaft” (Webb, at col. 2, ll. 35-36). Fig. 2a shows an example of a cylindrical shaft.
3. In one embodiment, the shaft is provided with circumferentially radiating flexible anchoring arms of varying radial extension which are adapted to secure the punctum plug within the punctum of a wearer (Webb, at col. 2, ll. 37-41; *see* Figs. 2a and 2b). Fig. 2b shows the arms having an increasing length (*see* Fig. 2b, elements designated 138a, 138b, 138c).
4. In another embodiment, “two preferably arcuate anchoring arms are provided at a distal portion of the shaft and extend outward and towards the head. The anchoring arms thereby function as barbs which retain the plug within the punctum” (Webb, at col. 3, ll. 7-11; at col. 5, ll. 54-62; *see* Figs. 5a and 5b).
5. “The punctum plug of the invention is preferably made from a highly flexible, resilient biocompatible material” (Webb, at col. 2, ll. 41-42).
6. “It should be appreciated that each of the arms is sufficiently flexible such that the arms will fold upward toward the head during insertion and

² The phrases “punctum plug” and “lachrymal plug” are used interchangeably throughout this Decision.

will accommodate even unusually narrow punctal openings” (Webb, at col. 4, l. 67 to col. 5, l. 3).

7. Webb states that the anchoring arms have different radial lengths to accommodate differently sized ducts. An example is shown of a shaft with arms of different lengths to aid in the retention of the plug “within even the largest punctum” but “adapted to fold to fit smaller punctum” (Webb, at col. 4, ll. 30-37).

8. Webb states that

while particular arrangements of anchoring arms have been disclosed, it will be appreciated that other arrangements may be used as well. . . . [W]hile particular shapes, sizes, and numbers of the anchoring arms have been disclosed, it will be understood that punctum plugs having more or fewer anchoring arms formed about the shaft in a variety of shapes and sizes can be similarly used.

(Webb, at col. 6, ll. 50-59.)

9. The anchoring arms can restrict lachrymal fluid flow with the duct (Webb, at col. 4, ll. 37-39).

10. The punctum plug optionally has an axial insertion bore adapted to fit an insertion tool (Webb, at col. 4, ll. 15-17).

Comparison between the Webb and the claimed invention

Claims 1 and 19

11. Independent claim 1 is drawn to a “lachrymal plug” for blocking the lachrymal ducts.

12. The plug comprises: (1) “a substantially cylindrical body having external lateral walls”; and (2) “flexible elements attached to the external wall.”

13. The flexible elements in claim 1 are “structured and arranged to straighten out when positioned to maintain said lachrymal plug.”

14. Independent claim 19 is a “method of positioning a lachrymal plug.”

15. The method comprises the step of “positioning in a lachrymal duct” a plug having the same features recited in claim 1, including flexible elements “structured and arranged to straighten out when positioned to maintain said lachrymal plug.”

16. Webb describes a punctum plug (FF1, 2). Appellants do not dispute that Webb’s punctum plug is the same type of device as the claimed lachrymal plug in that both block the tear duct when inserted into it.

17. Webb’s plug includes a cylindrical shaft (FF2), meeting the limitation of a lachrymal plug comprising (1) “a substantially cylindrical body having external lateral wall[s]” as in claims 1 and 19.

18. Webb’s plug also has circumferential or radially extending anchoring arms (FF3, 4) which are made of “highly flexible, resilient biocompatible material” (FF5). The anchoring arms meet the limitation of (2) “flexible elements attached to the external wall” recited in the claims.

19. Webb’s disclosure that the anchoring arms are made of

a resilient material (one that exhibits resilience, the capability of a body to recover its size and shape after deformation, see Merriam-Webster’s Collegiate Dictionary, 10th Ed., 2001) indicates that the arms are, in fact, structured and arranged to straighten out, or return to their unstressed position as illustrated in FIG 2b, retaining the implant in place [*see* FF4, 5]. Accordingly, the Webb disclosure meets the limitations of the claims.

(Ans. 8.) *See also* Webb expressly stating that the arms are “sufficiently flexible such that the arms will fold upward toward the head during insertion” (FF6).

Claims 2 and 20

20. Claims 2 and 20 require that the “flexible elements comprise radial pins.”

21. Webb describes embodiments in which the anchoring arms are shown as wedged-shaped radial extensions (FF4; *see* Webb’s Figs. 5a and 5b) – meeting the claimed limitation of “radial pins” (Ans. 9).

Claim 3

22. Claim 3 depends on claim 2 and recites that the pins are tilted in the direction of the nasal cavities.

23. Since the arms depicted in Webb’s Figs. 5a and 5b extend radially outwardly from the plug body (Ans. 4-5), they “tilt” outwardly towards and in the direction of the nasal cavities as in claim 3.

Claims 4-6

24. Claim 4 recites that the pins have a “constant length”; claim 5, that they have a “variable length”; and claim 6, that they have “an increasing or decreasing length.”

25. Webb teaches various embodiments, including plugs having two arms of constant length (FF4; *see* Figs. 5a and 5b) as in claim 4, arms of “variable length” (FF7) in claim 5, and increasing or decreasing length as in claim 6 (FF3).

Claim 7

26. Claim 7 depends on the claim 2 and states that “the pins are arranged in helical formation around the body” of the plug.

27. Webb describes embodiments in which “the anchoring arm is a single flange helically wound about the shaft” (Webb, at col. 3, ll. 1-3; *see also* col. 4, ll. 20-45; Figs. 4a and 4b).

Claim 8

28. Claim 8 is drawn to the “lachrymal plug according to claim 1 further comprising: at least one flexible disk arranged to ensure impermeability.”

29. Webb teaches that a plug can have a circumferential anchoring arms which restrict lachrymal fluid flow (FF9), therefore making the duct impermeable as required by the claim.

Claim 9

30. Claim 9 is directed to a plug of claim 1 having radial pins (depends claim 2 which depends on claim 1) which “have sufficient elasticity to partially penetrate into an inner wall of the lachrymal canaliculus by straightening.”

31. The anchoring arms described in Webb are flexible and resilient (FF5,6) and stick into the duct wall upon insertion to hold it in place (FF3,4), providing reasonable basis (*see* FF19) that the pins meet the claimed limitation.

Claim 11

32. Claim 11 recites that the “lachrymal plug according to claim 1” has “a cone, a double cone, or a diabolo shape.”

33. Webb describes a plug having a cone shape (*see* Webb, Figs. 2-7; Ans. 5).

Claim 18

34. Claim 18 is to the lachrymal plug of claim 1 “wherein the flexible elements are structured and arranged to collapse against the external walls to allow insertion of the lachrymal plug in the lachrymal duct and straighten when released in the lachrymal duct.”

35. The anchoring arms described in Webb are flexible and resilient (FF5,6) and stick into the duct wall upon insertion to hold it in place (FF3,4), providing reasonable basis (*see* FF19) that the arms meet the claimed limitation.

Analysis

The Examiner has the burden of establishing whether the prior art, expressly or inherently, describes all elements of the claimed invention as arranged in the claim. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d at 1369. In this case, it is not disputed that the lachrymal plug described by Webb has a substantial cylindrical body with attached flexible elements as required by claims 1 and 19 (FF16-18), the only two independent claims involved in this appeal. The primary issue is whether Webb teaches that the flexible elements are “structured and arranged to straighten out when positioned to maintain said lachrymal plug” as in claims 1 and 19.

The PTO does not have the ability “to manufacture products or to obtain and compare prior art products.” *In re Best*, 562 F.2d at 1255. Thus, once sound basis is provided for believing that the prior art accomplishes the same result which is claimed, the burden properly shifts to the applicant to show they are not. *See In re Spada*, 911 F.2d at 708. The Examiner takes the position that the description in Webb of anchoring arms made of a flexible, resilient material is sound basis for believing that the arms are “structured and arranged to straighten out when positioned to maintain said lachrymal plug” as recited in the claims (FF19). This position is based on factual findings supported in the record before us (e.g., FF5-6). As we find no flaw in the Examiner’s reasoning, we conclude that *prima facie* anticipation of claims 1 and 19 has been established.

Appellants argue “while disclosing an anchoring arm that can fold to accommodate narrow punctal openings, WEBB fails to disclose this anchor arm is *structured and arranged to straighten out when positioned to maintain the plug in position*” (App. Br. 9-10, 11).

While there is no express disclosure that the anchoring arms “straighten out,” Webb teaches that the anchoring arms retain the plug in the duct, acting as “barbs” to hold it in place (FF4). Thus, it is reasonable to believe that after folding the arms downward to facilitate entry into a duct (FF6), the arms – being made of resilient material (FF5) – would spring back to their original configuration in which the barbs would hold the plug in the duct. Thus, based on the totality of the evidence before us, we conclude that Appellants have not provided sufficient rebuttal arguments or evidence.

As to separately argued claim 2-6, 8, 9, 11, 18, and 20, we find that Webb’s disclosure would be reasonably understood by persons of ordinary skill in the art to describe the claimed features (FF20-25, 28-35). Other than to generally contend that such limitations are missing, Appellants have not identified any specific deficiency in Webb’s disclosure.

As to claim 7, we agree with Appellants that Webb does not describe pins arranged in a helical arrangement. Rather, Webb describes an anchoring arm in a single flange that is helically wound around the shaft (FF27). This description is not of pins in a helical arrangement as required by claim 7 (FF26).

OBVIOUSNESS IN VIEW OF WEBB AND MACKEEN

Claims 10, 15, and 21 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Webb and MacKeen (Ans. 5).

Findings of Fact

36. Claim 10 is drawn to the plug of claim 1 which comprises “an axial duct having a reduced passage for tears.”

37. MacKeen describes an axial bore that extends through a lachrymal plug (“lacrima^[3] fluid modulating device”) that “serves to meter the passage of lacrimal fluid through the punctal opening” (MacKeen, at col. 4, ll. 64-68; *see* Ans. 6).

38. MacKeen also teaches a “dilator/insertion tool” to insert the lachrymal device into the duct (MacKeen, at col. 6, ll. 53-59; Figs. 5A-5F; *see* Ans. 6).

39. The Examiner finds that “it would have been obvious to . . . modify the plug of Webb et al. to include an open axial duct as taught by MacKeen et al. [FF37] to meter the passage of lacrimal fluid (or tears) away from the eye, through the punctum while the plug was inserted” (Ans. 6).

40. Claim 21 is to the method of claim 19 further comprising “positioning the lachrymal plug with a tube having a push rod that is structured and arranged to allow pressing the pins against an outer wall of the cylindrical body and to release the pins once the lachrymal plug is in position.”

41. The Examiner finds that claim 21 limitation would have been obvious in view of Webb’s teaching that a tool can be utilized to insert its plug (FF10) and MacKeen’s teaching of such a tool and description of how to use it (FF38; Ans. 9).

Analysis

In making an obviousness determination, it is important to identify a reason that would have prompted persons of ordinary skill in the art to combine the elements in the claimed invention does. *KSR*, 127 S. Ct. at

³ lachrymal

1741. The Examiner satisfied this burden by providing an explanation as to why the skilled worker would have modified Webb's teaching to have made the claim invention as in claims 10 and 21 (FF39, 41).

As to claim 21, Appellants argue that "no special tools are necessary to facilitate insertion of the punctum plug of WEBB into the patient's punctum" (App. Br. 14). This argument is not persuasive. As found by the Examiner, Webb makes explicit mention of an insertion tool (FF10), thus providing a reason to have utilized an insertion tool, such as the tool described in MacKeen (FF41; Ans. 9).

For the foregoing reasons, and those set forth in the Answer on pages 9-10, we affirm the rejections of claims 10 and 21. Claim 15 was not separately argued, and therefore falls with claims 10 and 21. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS IN VIEW OF WEBB AND FREEMAN

Claims 12 and 13 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Webb and Freeman (Ans. 6).

Findings of Fact

42. Claim 12 is directed to a lachrymal plug of claim 1 which is made of metal; claim 13 is to a lachrymal plug made of shape memory metal.

43. Freeman teaches that a lachrymal plug can be made of metal (Freeman, at col. 4, ll-47-49).

44. Freeman also teaches that its plug can be of materials which are flexible (Freeman, at col. 4, ll. 27-36; Ans. 10).

45. Appellants do not dispute that shape memory metals are "well-known in the art of surgical implants" (Ans. 10).

46. The Examiner finds:

It follows from the combination of those disclosures that the Freeman disclosure contemplates the use of a flexible or resilient material for the implant, which may be constructed of a metal. . . . [T]he substitution of a flexible metal known in the art for the metal disclosed by Freeman would yield only predictable results. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a shape memory metal as suggested by Freeman for the resilient material disclosed by Webb, since such a combination would have yielded predictable results to one of ordinary skill in the art.

(Ans. 10.)

Analysis

Appellants state that Freeman “does not disclose flexible metal elements, such that it would not have been obvious to modify WEBB to be formed from metal” (App. Br. 16).

This argument does not persuade us that the Examiner erred. The Examiner provided a well-reasoned statement as to why persons of ordinary skill in the art would have utilized a flexible metal to produce Webb’s plug (FF46), i.e., that both Webb and Freeman describe flexible plugs and therefore it would have been logical to persons of ordinary skill in the art to choose a flexible metal when the plug is to be made of metal. Appellants have not identified a deficiency in this reasoning, and as we find none, we affirm the rejection of claims 12 and 13.

OBVIOUSNESS IN VIEW OF WEBB AND HERRICK

Claim 14 stands rejected under 35 U.S.C. § 103(a) as obvious in view of Webb and Herrick (Ans. 7).

Findings of Fact

47. Claim 14 is to the lachrymal plug of claim 1 “wherein the lachrymal plug comprises a radio-opaque reference that is visible with X-rays, to facilitate marking during its progression when it is positioned.”

48. Herrick teaches “a canalicular implant that may be made of a material that is responsive to X-rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50)”

(Ans. 7).

49. The Examiner finds that it

would have been obvious to . . . modify the implant of Webb et al. to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

(Ans. 7.)

Analysis

The Examiner has satisfied his burden of providing a reason that would have prompted persons of ordinary skill in the art to have combined Webb and Herrick to have made the claimed invention (FF49). We agree with this reasoning. Thus, we are not persuaded by Appellants’ argument that “the Examiner has not identified any articulable rationale in the applied art for combining these teachings” (App. Br. 18). We affirm the rejection of claim 14.

OBVIOUSNESS IN VIEW OF WEBB AND SEDER

Claims 16, 17, 22, and 23 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Webb and Seder (Ans. 7).

Findings of Fact

50. Claims 16, 17, 22, and 23 involve using an instrument with jaws to position or remove a lachrymal plug from the lachrymal duct.

51. Seder states that forceps can be used to insert and remove a lachrymal plug (Seder, at col. 3, ll. 58-60).

52. The Examiner finds that the forceps as described by Seder have jaws (Ans. 7). Appellants do not dispute this finding.

53. The Examiner also finds that it would have been obvious “to modify the method of insertion of Webb et al. to substitute the forceps as the tool, as taught by Seder et al., since Appellant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well” (Ans. 8; *see also* Ans. 11-12).

Analysis

The Examiner has satisfied his burden of providing a reason that would have prompted persons of ordinary skill in the art to have combined Webb and Seder to have made the claimed invention (FF53).

Appellants contend that because Webb does not teach that a special tool is necessary to remove the lachrymal plug, there would have no motivation to use Seder’s forceps (App. Br. 19).

This argument is not persuasive. As the Examiner thoroughly explained on pages 11-12 of the Answer, Webb specifically teaches that a tool may be utilized to insert a lachrymal plug (FF10; *see* Ans. 11). Seder

describes a specific tool that is useful for this purpose (FF51). Persons of ordinary skill in the art would have prompted to use Seder's forceps for its known usefulness in inserting and removing lachrymal plugs. Appellants do not identify a defect in this reasoning, and as we find none, we affirm the rejection of claims 16, 17, 22, and 23.

CONCLUSIONS OF LAW

Webb describes a lachrymal plug with "flexible elements" which are "structured and arranged to straighten out when positioned to maintain said lachrymal plug" as recited in claims 1 and 19. Webb also describes the limitations set forth in claims 2-6, 8, 9, 11, 18, and 20. We affirm the anticipation rejection of claims 1-6, 8, 9, 11, and 18-20.

Webb does not describe pins arranged in a helical arrangement as in claim 7. We reverse the anticipation rejection of claim 7.

Webb combined with the secondary references teaches the limitations in claims 10, 12-17, and 21-23. Accordingly, we affirm the obviousness rejections of claims 10, 12-17, and 21-23.

AFFIRMED-IN-PART

cdc

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